SECTION 2 - 510(K) SUMMARY

JUN 29 2007

Name and Address of Applicant
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Date: April 13, 2007

Contact:
Serrah Namini,
Regulatory Affairs Assoc. Director
(949) 580-1555 Ext. 4401
Fax: (949) 580-1550

- **Device Name:** Telemetry receiver
- **Trade or proprietary name:** ORG-9700A
- **The common or usual name:** Signal Exchanger and Telemetry Receiver
- **The classification:** Class II Special control; Detector and Alarm, Arrhythmia under 21 CFR Part 870.1025; Transmitter and Receiver Physiological Signal, Radio frequency under 21 CFR 870.2910
- **Legally Marketed Predicate:** ORG-9700 and ORG-9200A Multiple Patient Receiver per 510(k) #K002068, commercial distribution certification dated February 8, 2001

Description and Intended Use:

New ORG-9700A has the same intended use as the previously marketed telemetry system, which is for use by medical professionals with Nihon Kohden telemetry transmitters and central stations to provide cardiac and vital signs monitoring for multiple patients. The device can receive the patient's ECG, respiration, SpO_2, and non-invasive blood pressure data (NIBP value is only displayed on the central monitor) from a transmitter and send it to Nihon Kohden Central monitor within the medical facility. The device is designed as a component of a central monitor network to be used in the ICU, CCU, HCU, recovery room, operating room and general ward. The device will receive and transmit physiological data from telemetry transmitters/receivers and generate an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected.

The device is not sterile. The device is not directly connected to patients. It is used as a central monitoring system for obtaining a series of patient vital information.

The device was subject to electromagnetic, environmental, safety and performance testing procedures. Software validation was satisfactory completed as part of product's design validation. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the ORG-9700A Multiple Patient Receiver is substantially equivalent to the Nihon Kohden predicate Multiple Patient Receivers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Nihon Kohden America, Inc.
c/o Serrah Namini
Regulatory Affairs, Associate Director
90 Icon St.
Foothill Ranch, CA 92610

Re: K071058
Trade/Device Name: ORG-9700A Multiple Patient Receiver and accessories
Regulation Number: 21 CFR 870. 2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: May 29, 2007
Received: June 7, 2007

Dear Ms. Namini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K071058

Device Name: ORG-9700A Multiple Patient Receiver

Indications for Use:

The ORG-9700A Multiple Patient Receiver is intended for use by medical professionals with Nihon Kohden telemetry transmitters and central stations to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The device detects patient vital sign alarm conditions and includes an algorithm to detect cardiac arrhythmias. The intended use of the modified device has not changed as a result of the modifications. The device is available for use on all patient populations.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer
n Sign-Off)
n of Cardiovascular Devices
Number K071058